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DATE:	April 28, 2010
To:	**Examiner Nina A. Archie and Supervisory Examiner Robert B. Mondesi**
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Our Ref. No.:	SYNI-003CN
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PROPOSED AGENDA FOR IN-PERSON INTERVIEW

Date: April 29, 2010 Time: 10:30 AM

Attendees: Amy Mandragouras, Dr. Irwin Scher, and Dr. Jimmy Mond

Examiner: Nina Archie

U.S. Serial No.: 10/601,171 Filed: June 23, 2003

Title: OPSONIC MONOCLONAL AND CHIMERIC ANTIBODIES SPECIFIC FOR LIPOTEICHOIC ACID OF GRAM POSITIVE BACTERIA

Docket No.: SYNI-003CN

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1. Consideration of draft claim amendments

2. Discussion of 35 U.S.C. § 112 written description rejection

   (i) Legal framework
   - Case law and Board of Appeals precedent is well documented and unambiguous –all that is required for an adequate written description of an antibody is the disclosure of a fully characterized antigen, in this case, LTA.

   (ii) Prevention of staphylococcal infections
   - Passive immunization of the claimed composition of monoclonal antibodies prior to staphylococcal infection in humans and in animal models is disease prevention as shown by an increase in neonatal survival and prevention of bacteremia.

   (iii) Structure of LTA from gram positive bacteria
   - LTA is a fully characterized antigen, of uniform structure on diverse Gram positive organisms and has been synthetically synthesized both in the form of LTA and in the form of polyglycerol phosphate.

(iv) **Genus of antigenic determinants/immunoepitopes**

- The claimed invention is not a vaccine in which an epitope from a protein antigen is used to induce active immunity, but rather a composition of monoclonal antibodies specifically reactive with LTA. Because LTA is a linear polymer composed of repeating units of poly-glycerol phosphate, it represents a small number of well defined epitopes.

3. Discussion of 35 U.S.C. § 112 enablement rejection

(i) **Nature of the invention**

- The claimed invention is directed to monoclonal antibodies of IgG isotype specifically reactive with poly-glycerol phosphate of LTA

(ii) **Breadth of the claims**

- The claims are composition claims which recite an amount of anti-LTA monoclonal antibodies effective to prevent infection in neonates by binding and enhancing opsonization of multiple Gram-positive organisms including *S. epidermidis* and *S. aureus*. The level of skill in the art of monoclonal antibodies is high.

(iii) **Guidance in the specification**

- The techniques for making antibodies are routine in the art, and require no undue experimentation. The specification provides ample guidance for producing the presently claimed antibodies and has working examples demonstrating protection against staphylococcal infection by increasing survival of neonatal animals.

(iv) **State of the art**

- The use of antibodies as a prophylactic agent to prevent or reduce the effects of an infection is well established in the art. Indeed, antibody compositions have been successfully used to treat or prevent infection in humans by a wide variety of pathogenic agents including viruses, bacteria, and toxins.